BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

As rescanning documents *will not* correct images, please do not report the images to the Image Problem Mailbox.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/887,593	06/21/2001	Daniel E. Afar	G&C 129.18USD1	9040

7590 05/14/2003

Attention of Karen S. Canady
Gates & Cooper LLP
Howard Hughes Center
6701 Center Drive West, Suite 1050
Los Angeles, CA 90045

EXAMINER
NICKOL, GARY B

ART UNIT	PAPER NUMBER
1642	10

DATE MAILED: 05/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/887,593	AFAR ET AL.	
	Examiner	Art Unit	
	Gary B. Nickol Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 April 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *72-89* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *72-89* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Applicants' response (Paper No. 9) to the notice of non-responsiveness (Paper No. 8) has been received and has been carefully considered. To the extent that applicants argue that BPC-1 and 19P1E8 are one and the same, such arguments have been found persuasive. To the extent that applicants argue that the new claims, as submitted, fall within the scope of the elected group, such argument are not found persuasive for the reasons of record in Paper No. 8. However, upon reconsideration, and in view of the newly added claims, the restriction requirement mailed 8-21-02 is withdrawn in favor of a new restriction requirement as set forth below.

Claims 72-89 are pending

Election/Restrictions

Upon review and reconsideration, restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claim 72, as solely drawn to an *in-vitro* method of modulating cells comprising administering an altering composition whereby the composition alters the status of 19P1E8 or alters the status of a molecule that is modulated by 19P1E8, classified in class 435, subclass 4.

II. Claims 73-76, as solely drawn to an *in-vitro* method of modulating cells comprising administering an antibody that specifically binds to 19P1E8, classified in class 435, subclass 7.1.

III. Claim 77, as solely drawn to an *in-vitro* method of modulating cells comprising administering a ribozyme that cleaves RNA essential for expression of 19P1E8, classified in class 435, subclass 91.31.

IV. Claim 78, as solely drawn to an *in-vitro* method of modulating cells comprising administering an antisense polynucleotide to an RNA essential for expression of 19P1E8, classified in class 435, subclass 6.

V. Claim 79, as solely drawn to an *in-vitro* method of modulating cells comprising administering a substance that inhibits the secretion of 19P1E8 from said cells, classified in class 435, subclass 4.

VI. Claim 80, drawn to method of treating a subject comprising cells that express 19P1E8 comprising administering an altering composition which alters the status of 19P1E8 or alters the status of a molecule that that is modulated by 19P1E8, classified in class 514, subclass 1.

VII. Claims 81-84, as solely drawn to method of treating cancer in a subject comprising administering an antibody which specifically binds to a 19P1E8 protein, classified in class 424, subclass 130.1.

VIII. Claim 85, as solely drawn to method of treating cancer in a subject comprising administering a ribozyme that cleaves RNA essential for expression of 19P1E8, classified in class 424, subclass 94.1.

IX. Claim 86, as solely drawn to method of treating cancer in a subject comprising administering an antisense polynucleotide, classified in class 514, subclass 44.

X. Claim 87, as solely drawn to method of treating cancer in a subject comprising administering a substance that inhibits the secretion of 19P1E8, classified in class 514, subclass 1.

XI. Claim 88, as solely drawn to method of treating cancer in a subject comprising administering a 19P1E8 protein, classified in class 424, subclass 184.1.

XII. Claim 89, as solely drawn to method of treating cancer in a subject comprising administering a polynucleotide that comprises a 19P1E8 protein coding sequence, classified in class 514, subclass 44.

The inventions are distinct, each from the other because of the following reasons:

The inventions of Groups I-XII are *materially* distinct methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success. For example, the method of Groups I-V differ from the methods of Groups VI-XII in that the latter groups would differ in the dosage, schedules, and response variables since such groups are specifically drawn to methods of treating a subject *in-vivo*. Further, individually, the methods of Groups I-V and VI-XII, differ each from the other, in that distinctly different reagents and steps are required which differ in classifications as set forth above and would require different searches and the consideration of different patentability issues. For example, the method of Group VII would require the search and examination of issues regarding the patentability of antibody-based therapies while the method of Group IX would require distinctly different issues regarding the patentability of gene therapy.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Furthermore, because these inventions are distinct for the reasons given above and the search required for one group is not required for another group, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 703-305-7143. The examiner can normally be reached on M-F, 8:30-5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Gary B. Nickol, Ph.D.
Examiner
Art Unit 1642

GBN
May 9, 2003

Gary Nickol